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Jerome Asius

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10/05/2009

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EXAMINER

KASSA, TIGABU

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,544	Applicant(s) ASIUS ET AL.	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-37 is/are pending in the application.
- 4a) Of the above claim(s) 34, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/02/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-37 are pending. Claims 14-33 and 35 are under consideration in the instant office action. Claims 34 and 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-13 are cancelled.

Election/Restrictions

Applicant's election with traverse of Group I (claims 14-33 and 35) in the reply filed on 07/08/09 is acknowledged. The traversal is on the ground(s) that serious burden is not established by the examiner and the inventions do not lack the same or corresponding special technical feature. Additionally, applicant also argued that the teaching by WO 93/15721 does not anticipate instant claim 14 because the ceramics disclosed by the prior art is non-resorbable. Furthermore, applicant also argues that the examiner is forcing applicant to pay duplicative fees by not examining all the inventions together. These arguments are not found persuasive because the examiner has established a search and examination burden by breaking unity between each Group. As written any biodegradable compound with pseudoplastic properties read on instant claim 14, for example, polysaccharides. The prior art WO 93/15721 indeed discloses a permanent biocompatible material comprising a matrix of spherical particles of biocompatible ceramic material wherein the augmentation material is homogeneously suspended in a biocompatible **resorbable** gel carrier comprising a polysaccharide (see abstract). Therefore, the argument about fees is irrelevant since the proper guidelines are applied for breaking unity.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09/02/05 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note: Instant claims 15-16 are included in the rejection since they depend on indefinite base claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of

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the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the implant comprise at least one biodegradable thixotropic compound (the broadest range) and even more preferably at least one thixotropic compound with pseudoplastic properties based on xanthan gum (the narrower range). With regard to instant claim 32 the broader range is the molecular weight of greater than one million Daltons whereas the narrower range is preferably from 1 million to five million Daltons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Agerup (US Patent No. 5633001).

Instant claim 14 recites an implant for subcutaneous or intradermal injection into fibrous tissue, comprising at least one biodegradable thixotropic compound with pseudoplastic properties, preferably at least one bioresorbable thixotropic compound with

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pseudoplastic properties, and even more preferably at least one thixotropic compound with pseudoplastic properties based on xanthan gum. Instant claim 15 recites the implant according to claim 14, comprising at least one bioresorbable thixotropic compound with pseudoplastic properties. Instant claim 16 recites the implant according to claim 14, comprising at least one thixotropic compound with pseudoplastic properties based on xanthan gum.

Agerup discloses a biocompatible composition for tissue augmentation, comprising a **pseudoplastic polymer** carrier in an amount of 0.05-50% (w/w) of the total composition; and one or more tissue augmenting substances(s)(see abstract). Agerup also discloses the invention comprises a method for tissue augmentation, comprising: injecting the above composition into a desired site of the human or animal body for augmenting the tissue at and around said site (see abstract). Agerup discloses that the biocompatible carrier gel of the composition comprises a polymer dissolved in a suitable solution, such as physiological saline, as a matrix (column 2, lines 45-47). The polymer is selected from the group consisting of glucose amine glucans, such as **hyaluronic acid, hydroxy ethyl cellulose, carboxy methyl cellulose, xantahn gum, and alginates** (column 2, lines 48-51, see claims 1-2). Preferably, the matrix comprises 0.05-50% (w/w) of the composition (column 2, lines 52-53). This carrier gel according to the invention has pseudoplastic properties, ie it has shear thinning properties (column 2, lines 53-55). These teachings anticipate instant claims 14-16.

Claims 17-21, 24-26, 29-31, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubbard et al. (US Patent No. 7060287).

Instant claim 17 recites an implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of at least one biocompatible ceramic compound in suspension in at least one vector fluid, said implant being such that said microparticles are biodegradable and have a size of from 10 to 80 μm , said ceramic compound comprising at least one component chosen from the group formed by tricalcium phosphate (βTCP) and biphasic products (BPC) which comprise HAP and βTCP in variable proportion, and in that said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties. Instant claim 18 recites the implant according to claim 17 wherein the ceramic component is tricalcium phosphate (βTCP). Instant claim 19 recites the implant according to claim 17 wherein said microparticles have a size of from 15 to 50 μm . Instant claim 20 recites the implant according to claim 17 wherein said vector fluid comprises at least one bioresorbable thixotropic compound with pseudoplastic properties. Instant claim 21 recites the implant according to claim 17 wherein said vector fluid comprises at least one thixotropic compound with pseudoplastic properties based on xanthan gum. Instant claims 24-26 recite the implant according to claim 17 wherein the microparticles are bioresorbable, once the implantation has been made into a fibrous tissue, within a period of from 2 to 36 months, 3 to 24 months, and 4 to 18 months respectively. Instant claims 29-30 recite the implant according to claim 17 wherein the vector fluid for the implant is a biocompatible gel and a bioresorbable gel respectively. Instant claim 31 recites the implant according to claim 17 wherein the hyaluronic acid-based compound predominantly comprises hyaluronic acid. Instant claim 35 recites the implant as claimed in claim 14 or as claimed in claim 17, wherein said implant is in the

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form of a ready-to-use prefilled syringe, a ready-to-use prefilled bottle or a lyophilizate to be reconstituted.

Hubbard et al. disclose a permanent, **biocompatible** material for soft tissue augmentation (see abstract). The biocompatible material comprises a matrix of smooth, round, finely divided, substantially spherical particles of a biocompatible ceramic material, close to or in contact with each other, which provide a scaffold or lattice for autogenous, three dimensional, randomly oriented, non-scar soft tissue growth at the augmentation site (see abstract). The augmentation material can be homogeneously suspended in a biocompatible, **resorbable** lubricious gel carrier comprising a polysaccharide (see abstract). Hubbard et al. disclose that the augmentation material comprises smooth rounded, substantially spherical, particles of a ceramic material (column 5, lines 11-13). Hubbard et al. also disclose that the particles must be sufficiently small so as to avoid aggregation and clogging of the syringe when being injected (column 5, lines 27-29). A typical range for injection is from about 35 to 150 microns, preferably in a narrow particle size range extending not more than about 35 microns, and more preferably extending not more than about 10 to 30 microns, and-most preferably having substantially equivalent particle sizes (column 5, lines 31-34). Hubbard et al. disclose useful ceramic materials include tricalcium phosphate (column 7, line 45). Hubbard et al. also disclose the particulate ceramic material can be suspended in a biocompatible, resorbable lubricant, such as a polysaccharide gel to improve the delivery of the augmentation material by injection to the tissue site where augmentation is desired (column 10, lines 13-16). Suitable polysaccharides include hyaluronic acid, hyaluronic acid and xanthan etc (column 10, lines 21 and 30). Hubbard et al. also disclose in the

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tissue augmentation material and method of the present invention, other polysaccharides can also be included or used separately such as xanthan gum (column 12, lines 38-39 and 44). With regard to instant claims 24-26 as long as the prior art product anticipates the instantly claimed product, the prior art product is capable of being bioresorbable for the durations recited in claims 24-26. Hubbard et al. also disclose the augmentation material can easily be injected through an 18 gauge or smaller syringe intradermally or subcutaneously (column 14, lines 5-7). These teachings anticipate instant claims 17-21, 24-26, 29-31, and 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 22-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) as applied to claims 17-21, 24-26, 29-31, and 35 above, and further in view of Janas et al. (US Patent No. 6451059).

Applicant Claims

The claimed subject matters of instant claim 17 are set forth above. Instant claim 22 recites the implant according to claim 17 wherein said ceramic compound has a specific surface area of from $0.5 \text{ m}^2/\text{g}$ to $100 \text{ m}^2/\text{g}$. Instant claim recites the implant according to claim 17 wherein said ceramic compound has a specific surface area of from $2 \text{ m}^2/\text{g}$ to $27 \text{ m}^2/\text{g}$. Instant claim 27 recites the implant according to claim 17 wherein the microparticles are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%. Instant claim 28 recites The implant according to claim 17 wherein the microparticles are present in the vector fluid in a weight/volume proportion from 2% to 12%.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al. are set forth above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Hubbard et al. do not explicitly teach the surface area and amount of the ceramic material. These deficiencies are cured by the teachings of Janas et al.

Janas et al. teach a hard tissue scaffold comprising a resorbable ceramic (see abstract). Janas et al. teach in illustrative example particles of ceramic tricalcium phosphate, $\text{Ca}_3(\text{PO}_4)_2$, with a BET surface area of $1.708 \text{ m}^2/\text{gm}$, were milled in water containing a sodium silicate surfactant to create dispersion.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the **biocompatible** material of Hubbard et al. via the incorporation of ceramic particles with surface areas as specified in the instant claims 22-23 , because Janas et al. teach the incorporation of particles of ceramic tricalcium phosphate with a BET surface area of $1.708 \text{ m}^2/\text{gm}$. The skilled artisan would have been motivated to optimize the surface area of the particles because in such injectable implants particle sizes and surface areas control whether the biocompatible material will be injectable using syringes. Additionally, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the

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prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Janas et al., because both references teach similar biocompatible materials that can be used for tissue augmentation.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 27-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) as applied to claims 17-21, 24-26, 29-31, and 35 above, and further in view of Draenert (US Patent No. 4373217).

Applicant Claims

The claimed subject matters of instant claim 17 are set forth above. Instant claim 27 recites the implant according to claim 17 wherein the microparticles are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%. Instant claim 28 recites the implant according to claim 17 wherein the microparticles are present in the vector fluid in a weight/volume proportion from 2% to 12%.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al. are set forth above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Hubbard et al. do not explicitly teach the amount of the ceramic material. This deficiency is cured by the teachings of Draenert.

Draenert teach an implantation material comprises a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture thereof, and 5-35% by weight of resorbable tricalcium phosphate of a particle size of 50-300 μm , and an available pore volume of less than 0.1 ml/g (see abstract).

Draenert teach that among the special advantages of the implantation materials is the fact that the bond of the basic acrylate polymer is not negatively affected by the addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the amount of the ceramic material such as tricalcium phosphate, because Draenert teach the incorporation of particles of tricalcium phosphate in amounts of 5-35% of the composition used to make the implant material. The skilled artisan would have been motivated to add the ceramic material such as the tricalcium phosphate in amounts as recited because Draenert teach smaller amounts of the bond of the basic acrylate polymer is not negatively affected by the addition of this invention, due to the relatively low amounts of tricalcium phosphate added (column 2, lines 54-58). Additionally, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re

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Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Draenert, because both references teach similar biocompatible materials that can be used for implantation.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. (US Patent No. 7060287) as applied to claims 17-21, 24-26, 29-31, and 35 above, and further in view of Gertzman et al. (US Patent No. 7019192).

Applicant Claims

The claimed subject matters of instant claims 17 and 31 are set forth above. Instant claim 32 recites the implant according to claim 31 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of greater than one

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million daltons and preferably from one million to five million daltons. Instant claim 33 recites the implant according to claim 31 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of from one million to five million daltons.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hubbard et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Hubbard et al. teach both hyaluronic acid and hyaluronic acid and xanthan as polysaccharide gel types incorporated as a carrier, Hubbard et al. do not explicitly teach molecular weights of the hyaluronic acid. This deficiency is cured by the teachings of Gertzman et al.

Gertzman et al. teach a formable bone composition for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles (see abstract). The particle size ranges from about 0.1 mm to about 1.0 cm and is mixed in a hydrogel carrier containing a sodium phosphate saline buffer, the hydrogel component of the carrier ranging from about 1.0 to 5.0% of the composition and a pH between 6.8 7.4 with one or more additives of a cellular material, growth factor, demineralized bone chips or mineralized bone chips (see abstract). The primary role of a carrier is to serve as a delivery vehicle (column 6, lines 45-46). The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such Sodium Hyaluronate (hyaluronic acid) 6.6×10^5 - 2.6×10^6 Daltons and its derivatives (column 7, lines 7-10).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the material of Hubbard et al. via the incorporation of hyaluronic acid based polysaccharides with molecular weights as specified, because Gertzman et al. teach the use of hyaluronic acid based polysaccharides with molecular weight as taught above for making materials for the purpose of bone growth. The skilled artisan would have been motivated to incorporate hyaluronic acid based polysaccharides with molecular weights as specified because Gertzman et al. teach that such a carrier can serve as a delivery vehicle (column 6, lines 45-46). The carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such as Sodium Hyaluronate (hyaluronic acid) 6.6×10^5 - 2.6×10^6 Daltons and its derivatives (column 7, lines 7-10). Additionally, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). A skilled artisan would have had a reasonable expectation of success in combining Hubbard et al. and Gertzman et al., because both references teach similar biocompatible materials that can be used for the growth of bone.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

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Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

Claims 14-33 and 35 are rejected. Claims 34 and 36-37 are withdrawn. Claims 1-13 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

9/30/09

/Mina Haghighatian/
Primary Examiner, Art Unit 1616